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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,727	08/03/2001	Albert Orfao	3582/49121	5099

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EXAMINER

LAM, ANN Y

ART UNIT PAPER NUMBER

1641

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/920,727

Applicant(s)

ORFAO, ALBERT

Examiner

Ann Y. Lam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14, line 1, recites "the large particle". There is insufficient antecedent basis in the claim for this limitation. (It appears that claim 14 should recite --the large-capturing particle--.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chandler et al., 6,268,222, in view of Hansen, WO 00/11449.

Chandler discloses a process for isolating molecules, cells and other particles which are specifically bound to a large particle comprising:

incubating a sample with at least one set of large-capturing particles (i.e., microparticles, col., 3, line 9) each of which are able to specifically bind/capture a large number of molecules, cells or other particles contained in the sample (e.g., antigens, nucleic acids, col. 12, lines 58-64), said large-capturing particles being larger than 200 um (col. 3, lines 11-12;);

analyzing the large-capturing particles containing specifically bound molecules, cells or other particles (col. 15, lines 51-55);

and detaching the molecules, cells or other sample particles of interest from the larger-capturing particles after they are sorted (col. 16, lines 45-49.)

As to claim 2, said large-capturing particles may be of different sizes, materials, densities, and/or shapes (e.g., different shapes, col. 6, lines 18-21.)

As to claim 3, different types of molecules, cells or other particles can be bound to the large-capturing particles (col. 12, lines 58-61.)

As to claim 4, the large-capturing particles are covered with or bound to specific antibodies, parts of antibodies, oligonucleotides or other types of probes specific for the binding of the molecules, cells and other particles of interest (col. 12, lines 45-47, col. 12, lines 58-64.) (The Chandler microparticles, being covered with nanoparticles (col. 2, lines 64-66) that react with an analyte (such as an antibody, col. 12, lines 45-47, and col. 14, lines 64-65), are considered to be covered with or bound to antibodies.)

As to claim 5, the sample is simultaneously or sequentially incubated with two or more different sets of large-capturing particles for the isolation/depletion of two or more different types of molecules, cells or other particles from the sample (col., 3, lines 4-7,

col., 12, lines 53-57, and col. 17, lines 3-9, disclosing sets of microparticles with unique labels; and col. 4, lines 51-54, disclosing detection of multiple subpopulations of analytes in a sample.)

As to claim 6, each set of large-capturing particles can specifically bind one, two or more different types of molecules, cells or other particles from the sample (col. 14, lines 64-65.)

As to claim 7, the incubation of the sample with the large-capturing particles is performed by: (A) directly mixing the large-capturing particles with the sample (col. 14, lines 63-65, disclosing that a sample is combined with the microparticles.) (The combining step in Chandler is considered to be directly mixing the large-capturing particles with the sample.)

As to claim 8, the distinction between the large-capturing particles bound to the molecules, cells or other sample particles is based on their fluorescence (col. 15, line 52.)

As to claim 10, different sample volumes and amounts of large-capturing particles can be used in combination, (col. 16, lines 45-49.) Examiner notes that Applicant has not claimed from what the sample volumes and amounts of large-capturing particles are different. For examination purposes, Examiner interprets "different" to mean that the sample volumes and amounts of large-capturing particles can be any one of a variety of different volume or amount.

As to claim 12, the molecules are proteins (e.g., antibodies, col. 12, line 61.)

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As to claim 13, the other particles are chromosomes, mitochondria, zymogen granules or cell membranes (col. 12, line 63, disclosing cell separation.) The cell separation disclosed by Chandler is considered to be a disclosure of sorting cell membranes, since cells comprise membranes. In any case, the limitations in claim 13 refer to a limitation in claim 1 that is recited in the alternative (see claim 1, line 5, for example.)

As to claim 14, the large particle is polystyrene (col. 3, line 23.)

Chandler teaches use of the invention for affinity purification and cell separation, among other uses (col. 12, lines 63-64.) Chandler also teaches isolation of various products of interest, which are released from the complex by various salt solutions (col. 16, lines 45-49.) Chandler also teaches that the preferred method to detect, differentiate, sort, quantitate, and/or analyze the analytes in a sample is a flow cytometry (co. 4, lines 55-58.)

However, Chandler does not disclose the step of sorting from each other the large-capturing particles containing specifically bound molecules, cells or other particles (i.e., last step in claim 1), nor the step of sorting large-capturing particles bound to molecules, cells or other sample particles into Petri dishes or microtiter plates (claims 9 and 15.)

Hansen discloses a flow cytometer (see first sentence of abstract) for analyzing and dispensing objects (including objects having a diameter larger than 200 um, see page 19, lines 4-7) using a sorter (20', see page 26, lines 8-11) for diverting a portion of the sample stream into different destinations (page 26, line 9), such as into different

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microtiter plates (page 22, lines 17-18), based on a signal from a detector, such as a detector for a fluorescent label (page 25, lines 11-16), and a processor (page 23, line 2.)

Hansen also teaches that the invention can be utilized to sort large microspheres used in combinatorial chemistry to produce libraries of test compounds (page 37, lines 15-18.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the Hansen flow cytometer for affinity purification or cell separation in the Chandler method since Hansen teaches that the flow cytometer can be used with microspheres in combinatorial chemistry to produce libraries of test compounds, such combinatorial chemistry methods include affinity purification or cell separation such as that disclosed by Chandler. The Hansen flow cytometer provides the advantage of not only analyzing the microspheres but also sorting different microspheres, such as the differently labeled microparticles for the detection of multiple subpopulations of analytes in a sample taught by Chandler.

Response to Arguments

Applicant's arguments with respect to the above rejected claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hansen, 6,657,713, disclosing a flow cytometer with a sorter. Watkins et al., 6,280,618, disclosing simultaneous assays for different analytes, and Furlong et al., 6,482,652, disclosing a particle sorter.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L. 


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11/15/04